

**REMARKS**

**I. Amendments to the Specification**

On pages 2-3 of the Office Action of February 5, 2008, the Examiner requires deletion of “The present invention relates to” on line 1 of the Abstract. The Applicant has herein amended line 1 of the Abstract and deleted the last sentence as shown on page 2 of this response.

**II. Amendments to the Claims**

The Examiner has withdrawn claims 1, 6, 7, 8-13 from consideration.

**III. 35 USC 112, first paragraph**

Claims 2-5 are rejected under 35 USC 112, first paragraph for claiming subject matter which was not described in the specification. On page 3 of the Office Action, the Examiner argues that “*There is no evidence that one would not ever get diabetes by consuming the claimed extract.*” The Applicant respectfully traverses as follows.

The Applicant notes that claims 2-5 are drawn to “*A composition for the prevention and treatment of diabetic complications* (emphasis added)...”. The claimed invention is not the prevention of diabetes that the Examiner argues cannot be prevented. The claimed invention as recited above is for the prevention and treatment of the complications caused by diabetes. Accordingly, the Applicant submits that claims 2-5 are supported throughout the specification, and, *inter alia*, at page 21, lines 10-36 to page 29, lines 1-6 under the subtitle “**Test Example 2: Effect of inventive herbal extract mixture on treatment of diabetic complications**” wherein the treatment of five different diabetic induced complications is tested. Accordingly, the Applicant submits that the claimed subject matter is thoroughly described in the specification and claims 2-5 are in compliance with 35 USC 112, first paragraph.

**IV. 35 USC 103(a)**

Claims 2-5 are rejected under 35 USC 103(a) as being unpatentable over the combination of Cho et al (US 2003/0194451 A1), Wang (CN 1273843), Zhang (CN 1151306), Yang (CN 1164401) and Sun (CN 1341441).

The Applicant respectfully disagrees and traverses this conclusion as falling far short of the

requirements for a proper 35 USC §103 rejection as set forth in the MPEP as well as the new *KSR v. Teleflex* Examination Guidelines of October 10, 2007.

Claims 2 and 3 recite, “*A composition for the prevention and treatment of diabetic complications, which contains...Euphorbiae radix, gingered Magnolia bark, parched Puerariae radix and Glycyrrhizae radix...*”.

Cho et al disclose a crude drug composition for treating gastrointestinal dyskinetic diseases comprising Magnoliae cortex and Glycyrrhiza Radix.

Wang discloses a gastrointestinal healthcare composition for treating a weak spleen and stomach, diarrhea, stomach-ache and superficial or chronic gastritis comprising *Pueraria* radix.

Zhang discloses a composition for treating gastropathies comprising *Euphorbiae* radix.

Yang discloses a composition for treating gastritis and duodenal ulcers by processing *Cortex Magnoliae Officinalis* with ginger water.

Sun discloses a composition for treating gastrointestinal disease comprising *Glycyrrhizae* radix.

The Applicant notes that there are a plethora of patents disclosing compositions for treating gastrointestinal disease (253 issued US patents) and gastritis (22 issued US patents), and that the skilled person wanting to prepare a composition for treating diabetic complications is not likely to look to any of them, let alone the applications cited in the Office Action by the Examiner. On page 8 of the Office Action the Examiner states, “*In the instant case, all of the above-listed ingredients were known for gastrointestinal care. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial for gastrointestinal health care.*”

Examiner’s statement is irrelevant to the novelty and obviousness of the claimed composition for

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the treatment of diabetic complications. One having ordinary skill in the art would not equate gastrointestinal disease and gastritis with diabetic complications. Furthermore, in view of all the possible art disclosing compositions for the treatment of gastrointestinal disease and gastritis, there is no motivation, either in the references or in the general knowledge in the art, for the skilled person to select the compounds of Cho et al, Wang, Zhang, Yang and Sun for preparing a compound comprising some of the disclosed ingredients for the treatment of diabetic complications.

The new KSR Guidelines provide that *“When making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness.”* There is an utter dearth of such factual findings in the present Action, and in their stead only citation of irrelevant references for compounds for treating entirely different and unrelated ailments.

The Guidelines further admonish that *“Although a rejection need not be based on a teaching or suggestion to combine, a preferred search will be directed to finding references that provide such a teaching or suggestion if they exist.”* There is no such motivation, either in the cited references or in the general knowledge in the art, as discussed above, and the Examiner has offered not one hint of where such motivation may be found.

The Applicant thus requests that the Examiner provide explicit statements of fact on the record that explain precisely why it would have been obvious that the skilled person would select the four claimed ingredients from each of the five cited references and combine them in the claimed ranges to prepare a compound for the treatment of diabetic complications as recited in the pending claims.

In view of the above, the Applicant submits that claims 2-5 are patentable under 35 USC 103(a) over Cho et al., Wang, Zhang, Yang and Sun.

**V. Conclusion**

The Applicant has complied with each and every requirement in the pending Office Action, and requests allowance of the pending claims. All amendments and remarks herein are made without prejudice.

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The Commissioner is authorized to charge any additional fees which may be required or credit overpayment to deposit account no. 12-0415. In particular, if this response is not timely filed, then the Commissioner is authorized to treat this response as including a petition to extend the time period pursuant to 37 CFR 1.136 (a) requesting an extension of time of the number of months necessary to make this response timely filed and the petition fee due in connection therewith may be charged to deposit account no. 12-0415.

I hereby certify that this paper (and any enclosure referred to in this paper) is being transmitted electronically to the United States Patent and Trademark Office on

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April 30, 2008

(Date of Transmission)

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Stacey Dawson

(Name of Person Transmitting)

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/Stacey Dawson/

(Signature)

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April 30, 2008

(Date)

Respectfully submitted,

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